Initial Approval Date: July 8, 2020 Revised Date: October 14, 2020

CRITERIA FOR PRIOR AUTHORIZATION

Migraine Acute Treatment Agents

BILLING CODE TYPE

For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES

Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in Table 1 below.

Celecoxib (Elyxyb™) Lasmiditan (Reyvow™) Rimegepant (Nurtec™) Ubrogepant (Ubrelvy™)

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- Patient must not have any unresolved/unaddressed red flag headache symptoms (examples listed in Table 3).^{3,4}
- For all agents listed, the preferred PDL drug, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Patient has a diagnosis of migraines that meet ICHD-3 criteria.¹
- Patient must have <2 migraines per week. ²⁻⁴ If a patient has ≥2 migraines²⁻⁴ per week or ≥4 migraines per month¹, the patient must be actively on prophylactic treatment.
- Prescriber has determined that the pain intensity of the patient's migraine attacks is moderate or severe.
- Patient must have experienced an inadequate response after a trial (at least 2 weeks) of 2 different triptans at a maximum tolerated dose, OR have a documented intolerance or contraindication to all agents within this class listed in Table 2.²⁻⁶
 - Prescriber must provide details of all previous medication trials. Documentation must include the medication name(s), trial date(s) and outcome(s) of the trial (i.e. inadequate response, intolerance or contraindication).
- Patient must have a baseline assessment on one of the following:
 - Migraine Treatment Optimization Questionnaire [mTOQ-5]^{2,7}
 - Migraine Disability Assessment Tool [MIDAS]

CRITERIA FOR RENEWAL: (must meet all of the following)

- Dose must not exceed limit in Table 1.
- Patient must meet all of the following:
 - o Migraines occurring < 2 times per week and < 4 times per month or actively on prophylactic therapy. ²⁻⁴
 - For patients who continue having ≥2 migraines per week or ≥4 migraines per month²⁻⁴, prescriber must provide details of how prophylactic treatment has been optimized since last approval.
 - o Patient must have a 50% improvement in one of the following:
 - mTOQ-5
 - MIDAS
- The patient has not required the addition of any other acute treatment agent used for migraine headache.²

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 6 months

APPROVED PA Criteria

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

• THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 6 months

Table 1. FDA-approved age and dosing limits for Migraine Acute Treatment Agents. 8-11

Agents	Indication(s)	Age	Dosing Limits*		
Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists					
Rimegepant (Nurtec)	Acute treatment of migraine	≥18 years	75 mg orally once in 24 hours.		
Ubrogepant (Ubrelvy)	Acute treatment of migraine	≥18 years	200 mg orally per 24 hours.		
COX-2 Selective Nonsteroidal Anti-inflammatory Drug (NSAID)					
Celecoxib (Elyxyb)	Acute treatment of migraine	≥18 years	120 mg orally once in 24 hours.		
Serotonin 5-HT1F Receptor Agonist					
Lasmiditan (Reyvow™)	Acute treatment of migraine	≥18 years	One dose (50 mg, 100 mg, 200 mg) orally		
			once in 24 hours.		

^{*} For a maximum of 4 doses per month.^{1,3,6}

Table 2. Prior Acute Migraine Therapies.²⁻⁴

Triptans	Combination triptans and NSAIDs
Almotriptan (Axert)	Sumatriptan/naproxen (Treximet)
Eletriptan (Relpax)	
Frovatriptan (Frova)	
Naratriptan (Amerge)	
Rizatriptan (Maxalt)	
Sumatriptan (Imitrex)	
Zolmitriptan (Zomig)	

Table 3. Examples of Red Flag Headache Symptoms^{3,4}

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Change in headache pattern	
Neurologic signs or seizures	
New onset after age 50	
Persistent headache after Valsalva maneuver or exertion	
Progressively increasing severity	
Symptoms of systemic disorders (i.e. fever, hypertension, myalgia, weight loss)	
"Thunderclap" headache (maximum severity at onset)	

Notes:

Reyvow	Tablets are available in two strengths: 50 mg, 100 mg. ⁹	
	The recommended dose of Reyvow is 50 mg, 100 mg, or 200 mg taken orally, as needed. No more than one dose should be taken in 24 hours. A second dose of Reyvow has not been shown to be effective for the same migraine attack. The safety of treating an average of more than 4 migraine attacks in a 30-day period has not been established. ⁹	

APPROVED PA Criteria References:

- 1. Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders,3rd edition. Cephalalgia. 2018;38:1-211. Available at https://ichd-3.org/.
- 2. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. Headache. 2019 Jan;59(1):1-18. Available at https://headachejournal.onlinelibrary.wiley.com/doi/full/10.1111/head.13456. Accessed on 6/17/20.
- 3. Acute Migraine Headache: Treatment Strategies. Am Fam Physician. 2018 Feb 15; 97(4):243-251. Available at https://www.aafp.org/afp/2018/0215/p243.html.
- 4. Treatment of acute migraine headache. Am Fam Physician. 2011 Oct 1;84(7):738]. Am Fam Physician. 2011;83(3):271-280. Available at https://www.aafp.org/afp/2011/0201/p271.html.
- 5. Headaches in over 12s: diagnosis and management. Updated Feb 2020. Available at: https://www.nice.org.uk/guidance/cg150. Accessed 6/5/20.
- 6. The Acute Treatment of Migraine in Adults: The American Headache Society Evidence Assessment of Migraine Pharmacotherapies. Headache: The Journal of Head and Face Pain 55.1 (2015): 3-20.
- 7. Validity and reliability of the migraine-treatment optimization questionnaire. Cephalalgia 29.7 (2009): 751-759.
- 8. Reyvow (lasmiditan) [prescribing information]. Indianapolis, IN: Lilly USA, LLC; July 2020.
- 9. Nurtec ODT (rimegepant) [prescribing information]. New Haven, CT: Biohaven Pharmaceuticals Inc; August 2020.
- 10. Ubrelvy (ubrogepant) [prescribing information]. Madison, NJ: Allergan USA Inc; December 2019.
- 11. Elyxyb (celecoxib) oral solution [prescribing information]. India: Dr. Reddy's Laboratories Limited; May 2020.

DRUG UTILIZATION REVIEW COMMITTEE CHAIR	PHARMACY PROGRAM MANAGER	
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	KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT	
DATE	 —	